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| APPLICATION NO.           | FILING DATE                           | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |  |
|---------------------------|---------------------------------------|----------------------|---------------------|------------------|--|
| 10/582,021                | 04/02/2007                            | Matthias Lau         | SGM-100-A           | 1809             |  |
|                           | 48980 7590 06/25/2009<br>YOUNG BASILE |                      |                     | EXAMINER         |  |
| 3001 WEST BI<br>SUITE 624 | G BEAVER ROAD                         | NGUYEN, SANG H       |                     |                  |  |
| TROY, MI 48084            |                                       |                      | ART UNIT            | PAPER NUMBER     |  |
|                           |                                       |                      | 2886                |                  |  |
|                           |                                       |                      |                     |                  |  |
|                           |                                       |                      | NOTIFICATION DATE   | DELIVERY MODE    |  |
|                           |                                       |                      | 06/25/2009          | ELECTRONIC       |  |

# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@youngbasile.com audit@youngbasile.com

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Application No.                                                   | Applicant(s)          |  |  |  |  |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------|-----------------------|--|--|--|--|
| Office Action Comments                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 10/582,021                                                        | LAU, MATTHIAS         |  |  |  |  |
| Office Action Summary                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Examiner                                                          | Art Unit              |  |  |  |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Sang Nguyen                                                       | 2886                  |  |  |  |  |
| The MAILING DATE of this communication app<br>Period for Reply                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | ears on the cover sheet with the c                                | orrespondence address |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |                                                                   |                       |  |  |  |  |
| Status                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                   |                       |  |  |  |  |
| 1) Responsive to communication(s) filed on 12 De                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | ecember 2004.                                                     |                       |  |  |  |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                   |                       |  |  |  |  |
| · <u> </u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | / <del>-</del>                                                    |                       |  |  |  |  |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                   |                       |  |  |  |  |
| Disposition of Claims                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                   |                       |  |  |  |  |
| 4)⊠ Claim(s) <u>1-22</u> is/are pending in the application.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 4) Claim(s) 1-22 is/are pending in the application.               |                       |  |  |  |  |
| 4a) Of the above claim(s) is/are withdraw                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 4a) Of the above claim(s) is/are withdrawn from consideration.    |                       |  |  |  |  |
| 5) Claim(s) is/are allowed.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                   |                       |  |  |  |  |
| 6) Claim(s) <u>1-22</u> is/are rejected.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                   |                       |  |  |  |  |
| 7) Claim(s) is/are objected to.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                   |                       |  |  |  |  |
| 8) Claim(s) are subject to restriction and/or                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | election requirement.                                             |                       |  |  |  |  |
| Application Papers                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                   |                       |  |  |  |  |
| 9)☐ The specification is objected to by the Examiner.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                   |                       |  |  |  |  |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                   |                       |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                   |                       |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                   |                       |  |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                   |                       |  |  |  |  |
| Priority under 35 U.S.C. § 119                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                   |                       |  |  |  |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>                                                                                                                                                                                                                                                              |                                                                   |                       |  |  |  |  |
| Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date 10/27/07.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal Pa | te                    |  |  |  |  |

Application/Control Number: 10/582,021 Page 2

Art Unit: 2886

### **DETAILED ACTION**

### Information Disclosure Statement

The information disclosure statement (IDS) submitted on 10/27/06 has been entered. The submission is in compliance with the provisions of 37 CFR 1.97.

Accordingly, the information disclosure statement is being considered by the examiner.

## Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

### Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
  - (1) Field of the Invention.
  - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (i) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (I) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if

the required "Sequence Listing" is not submitted as an electronic document on compact disc).

With respect to present invention, applicant should provide all the "headings" as listed above into the specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

**Regarding claim 1** in lines 2 and 4; the term "or" is alternative.

Regarding claim 5 in lines 2 and 4, the phrase "or the like" or "in particular" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "or the like" or "in particular"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

### Claim Rejections - 35 USC § 102

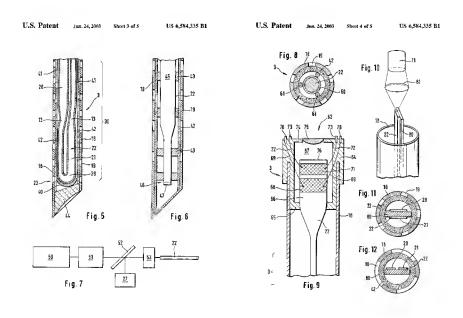
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-14, and 15-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Haar et al (U.S. Patent No. 6,584,335).

Regarding claim 1; Haar et al discloses a sensitive system (i.e., analysis device [1 of figure 1]) for detecting at least one of chemical and physical states or state changes within substance or mixtures of substances (abstract and col.2 lines 57 to col.3 line 13 and col.3 lines 33-47), comprising a sensitive membrane or layer (i.e., a spacer for a membrane [42 of figure 5]) is disposed on or in an element (i.e., a hollow needle [18 of figure 5]) replaceably connectable to a cannula (i.e., fiber track [20,21 of figures 4-5] and metal strip [56 of figure 4]), the element with cannula (18, 20, 21, 56 of figures 4-5) being introducible into a medium under measurement (i.e. sample liquid [abstract]) and forming an optical connection to an optical sensor system (i.e., analysis unit [4 of figure 1]). See figures 1-18



Regarding claim 2; Haar et al discloses the optical sensor system (4 of figures 1 and 7) has at least one optical detector (27 of figure 7) and a light source (50 of figure 7).

**Regarding claim 3**; Haar et al discloses the cannula is hollow (i.e., hollow needle [18 of figures 4-5]) throughout inside and forms an optical waveguide or at least one optical waveguide (i.e., optical fiber track [20, 21 of figures 4-5]) is guided through.

**Regarding claim 4**; Haar et al discloses state changes within a package are detectable with the layer by interferometry, using surface plasmon resonance, spectroscopic methods or luminescence intensity change.

Regarding claim 5; Haar et al discloses chemical concentrations, in particular at least one of hydrocarbon concentrations, hydrogen concentrations, oxygen concentrations, water content and physical parameters, in particular pressure or temperature, are detectable by layer thickness changes, luminescence changes, changes of refractive index or changes of absorption, transmission, reflectivity or the change of color of the layer or membrane (42 of figure 5 and col.4 lines 25-34 and col.5 lines 27-57 and abstract).

**Regarding claim 6**; Haar et al discloses one or more dyes or selective markers are contained in the membrane or layer (42 of figure 5 and col.10 lines 4-24).

**Regarding claim 7**; Haar et al discloses the marker or dye is sensitive (68, 71 of figure 9) dependently on concentration or dependently on one of temperature and pressure.

**Regarding claim 8**; Haar et al discloses the connectable element has a piercing protection (abstract and figures 4-6) and at least one opening (19 of figure 5).

**Regarding claim 9**; Haar et al discloses the connectable element comprises at least one optical element (i.e., a prismatic reflector [24 of figure 4]).

**Regarding claim 10**; Haar et al discloses the optical element is one of a fiber optic system, a GRIN lens, an optical rod, a disk or an optical lens (75 of figure 9).

**Regarding claim 11**; Haar et al discloses membrane or layer (42 of figure 5) is formed directly in or on one of a fiber optic system and a fiber optical system (20, 21, 22 of figure 5).

**Regarding claim 12**; Haar et al discloses membrane or layer (42 of figure 5) is incorporated directly into the hollow cannula (18 of figure 5).

**Regarding claim 13**; Haar et al discloses membrane or laver (42 of figure 5) is incorporated directly in the element (18 of figure 5) wherein said element is hollow (figures 4-6).

**Regarding claim 14**; Haar et al discloses membrane or layer (42 of figure 5) is an optical contact with a fiber optic (20, 21 of figure 5) or optical system.

**Regarding claim 16**; Haar et al discloses membrane or laver (42 of figure 5) is fixed on an adhesive film (i.e., drop for epoxy resin to seal [44 of figure 5]).

**Regarding claim 17**; Haar et al discloses a calibration (col.8 lines 6-17) can be effected upon closing by a defined change of the measured including one of a vacuum and an excess pressure, a supply of gas and a temperature change (col.12 lines 8-28).

It is noted that the language "one of a vacuum and an excess pressure, a supply of gas and a temperature change" is alternative (condition). Thus, the examining purposes, it is considered to be "a change temperature"

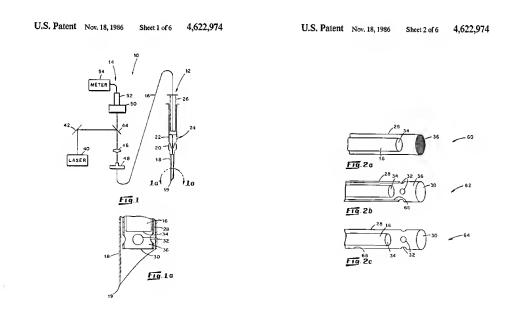
**Regarding claim 18**; Haar et al discloses at least one optical or chemical protective laver (col.10 lines 20-24) is applied to the membrane or laver (42 of figure 5).

Application/Control Number: 10/582,021

Art Unit: 2886

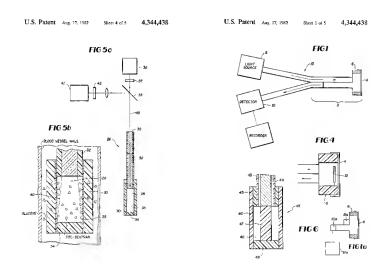
Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Coleman et al (U.S. Patent No. 4,622,974).

Regarding claim 1; Coleman et al discloses a sensitive system for detecting at least one of chemical and physical states or state changes within substance or mixtures of substances (col.7 lines50-68), comprising a sensitive layer (i.e., reflective surface [30 of figure 1a) is disposed on or in an element (i.e., exterior needle [18 of figure 1a]) replaceably connectable to a cannula (i.e., interior needle [28 of figure 1a]), the element (18 of figures 1 and 1a) with cannula (28 of figure 1a) being introducible into a medium (figure 1 and col.1 line 38 to col.2 line 14) under measurement and forming an optical connection (16 of figure 1) to an optical sensor system (14 of figure 1). See figures 1-6.



Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Schultz (U.S. Patent No. 4,344,438).

Regarding claim 1; Schultz discloses a sensitive system (i.e., sensor system [26 of figure 5a) for detecting at least one of chemical and physical states or state changes within substance or mixtures of substances, ccomprising a sensitive layer (i.e., permeable layer [35 of figure 5a-5b) is disposed on or in an element (i.e., a cylindrical hollow dialysis fiber [30 of figure 5a-5b) replaceably connectable to a cannula (i.e., signal optical fiber [32 of figure 5a-5b]), the element with cannula (30, 32 of figures 5a and 5b) being introducible into a medium (col.3 lines 2-16 and figure 5b) under measurement and forming an optical connection to an optical sensor system (i.e., light source [36 of figure 5a] and a light detector [41 of figure 5a]).



Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 15 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haar et al (U.S. Patent No. 6,584, 335) in view of Falkenberg et al (U.S. Patent No. 5,576,211).

Regarding claim 15; Haar et al discloses all of features of claimed invention except for membrane or laver is applied to a filler. However, Falkenberg et al teaches that it is known in the art to provide membrane or laver is applied to a filler (col.10 lines 24-37). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine system of Haar et al with membrane or laver is applied to a filler as taught by Falkenberg et al for the purpose of discovering accurately chemical concentration involves only routine skill in the art.

Regarding claim 19; Haar et al discloses all of features of claimed invention except for at least one permeable metal and dielectric layer, lacquer layer, consisting of synthetic resin lacquer or acrylic lacquer, PTFE or PTFE-base protective layer is formed. It would have been obvious to one having ordinary skill in the art at the time the

invention was made to combine system of Haar et al with at least one permeable metal and dielectric layer, lacquer layer, consisting of synthetic resin lacquer or acrylic lacquer, PTFE or PTFE-base protective layer is formed, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a mastter of obvious design choice. In re Leshin, 125 USPQ 416.

Regarding claim 20; Haar et al discloses all of features of claimed invention except for at least one of the membrane or layer and the element to be slipped on is at least one of disinfectable and sterilizable. Falkenberg et al teaches that it is known in the art to provide at least one of the membrane or layer and the element to be slipped on is at least one of disinfectable and sterilizable (col.11line 52 to col.12 line 3). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine system of Haar et al with at least one of the membrane or layer and the element to be slipped on is at least one of disinfectable and sterilizable as taught by Falkenberg et al for the purpose of discovering accurately chemical concentration involves only routine skill in the art.

Claims 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haar et al (U.S. Patent No. 6,584335) in view of Epstein et al (U.S. Patent No. 6,595,979).

Regarding claims 21-22 Haar et al discloses all of features of claimed invention except for the element is adapted to be slipped or screwed onto the cannula for

connection, wherein the involves a Luer lock connection. However, Epstein et al teaches that it is known in the art to provide the element is adapted to be slipped or screwed onto the cannula for connection (figure 2), wherein the connection involves a Luer lock connection (col.10 lines 6-25). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine system of Haar et al with the element is adapted to be slipped or screwed onto the cannula for connection, wherein the involves a Luer lock connection as taught by Epstein et al for the purpose of discovering accurately chemical concentration involves only routine skill in the art.

#### Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Dorian et al (2003/0205538); Vetter et al (7331941); Weber et al (6859282); Schaupp et al (6770030); Honzawa et al (5523845); Melinyshyn et al (5389077; Mori (3814081).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sang Nguyen whose telephone number is (571) 272-2425. The examiner can normally be reached on 9:30 am to 7:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tarifur Chowdhury can be reached on (571) 272-2800 ext. 86. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 10/582,021 Page 12

Art Unit: 2886

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

June 22, 2009

/Sang Nguyen/ Primary Examiner, Art Unit 2886